Remarks/Arguments

After entry of this Amendment, claims 1-21, as amended, will be pending for the Examiner's review and consideration.

Claims 1 and 8 have been amended to recite that the effective amount of menthol is about 20% to about 99% by weight of the composition or solution. These amendments are supported, for example, on page 8, lines 22-23 of the application as filed.

Claims 13 and 15 has been amended to recite that the effective amount of menthol is sufficient to decrease the variability in the drug's bioavailability by about 10% or more, or 50% or more, of the relative standard deviation (CV%) of the area under the blood or plasma concentration versus time curve (AUC) when compared to a non-menthol containing formulation AUC, respectively. These amendments are supported, for example, on page 9, lines 6-16 of the application as filed.

Claim 17 has been amended to recite that the effective amount of menthol is sufficient to extend the time that the drug provides a therapeutically significant concentration in blood or plasma by one hour or more. This amendment is supported, for example, on page 9, lines 17-23 of the application as filed.

Claims 20 and 21 have been added. New claims 20 and 21 are supported, for example, on page 8, lines 17-21 of the application as filed.

No new matter has been added to the claims by these amendments.

In an Office Action mailed January 16, 2008, the Office has required restriction of the application to one of 4 groups of claims under 35 U.S.C. § 121 as follows:

I. Claims 1-6, drawn to a composition for improving the bioavailability of a drug comprising at least one poorly bioavailable drug dissolved in an effective amount of menthol, classified in class 514, subclasses 26 and 724, depending upon the drug used.

II. Claims 7-12, drawn to methods for improving the bioavailability of a drug, classified in class 514, subclasses 460 and 724, depending upon the drug used.

III. Claims 13-16, drawn to a method for reducing the variability of the bioavailability of a drug, classified in claim 514, subclasses 510 and 724, depending upon the drug used.

IV. Claims 17-19, drawn to a method for increasing the extent of time that a drug provides a therapeutically significant concentration in blood or plasma, classified

> in claim 514, subclasses 182 and 724, depending upon the drug used.

Office Action, p. 2.

Applicants hereby provisionally elect, with traverse, the claims of Group I, *i.e.*, claims 1-6, for prosecution in the application. Applicants also elect to prosecute new claim 20 along with Group I because new claim 20 depends from a claim included in Group I (claim 1). In addition, as to the poorly bioavailable drug, Applicants elect to prosecute the sub-genus "drug with low aqueous solubility," and the species cyclosporine. The claims of the elected Group I that read on the elected sub-genus and/or species are claims 1-6 and 20.

Applicants expressly reserve the right to file divisional application(s) encompassing the claims of non-elected Groups II-IV prior to issuance of this application. Further, Applicants expressly reserve the right to rejoin the claims of non-elected Groups II-IV upon allowance of one or more of the claims of elected Group I.

This election is made with traverse because it is believed that claims 1-21 can be regrouped into a single group. As the Examiner is aware, there are two criteria for a restriction requirement: (A) the inventions must be independent or distinct as claimed; and (B) there must be a serious burden on the Examiner. M.P.E.P. § 803(I) (8th ed., rev. 6, 2007). "If the search and examination of all the claims in an application can be made without serious burden, the examiner *must* examine them on the merits, even though they include claims to independent or distinct inventions." M.P.E.P. § 803 (8th ed., rev. 6, 2007) (emphasis added).

Applicants believe that examining claims 1-21 as a single group would not place a "serious burden" on the Examiner to search since all of the claims of the present application relate to compositions for improving the bioavailability of a drug that include menthol, as well as to use of those compositions for improving the bioavailability of a drug, reducing the variability of the bioavailability of the drug, and increasing the extent of time that the drug provides a therapeutically significant concentration in blood or plasma. Thus, the claims are sufficiently similar to make it possible to examine them with minimal search and extensive overlap of art. In addition, the art relevant for one group is likely to be highly relevant for the other groups.

For these reasons, in view of M.P.E.P. § 803, all the subject matter in Groups I-IV should be searched and examined together.

An action on the merits is respectfully requested.

No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

Dated: March 13, 2008

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